

Impact Health Policy Weekly

Framing the Week

The House and Senate are both in session and working to pass a Continuing Resolution (CR) to keep the government in operation past September 30. Last week after the House Republican leadership tried and failed to pass a six-month CR along with Trump-backed legislation that would require proof of citizenship to vote, Speaker Mike Johnson (R-LA) began to negotiate with the Democrats and the Senate leadership on a CR that would actually pass. Over the weekend, leadership on both sides of the Capitol agreed on the 49-page CR ([full text/ section by section](#)) that will extend funding for government operations until December 20th of this year.

In addition to keeping all government agencies funded at current levels, the CR also includes some health care provisions including extending the availability of funding to implement the surprise billing law enacted in late 2020 and delaying pending clinical laboratory payment cuts under Medicare. The bill also provides \$231 million in additional funding for the Secret Service and funding for the presidential inauguration and presidential transition period. There is no disaster aid included or funding for Baltimore's Francis Scott Key Bridge, punting both of those funding decisions until after the election.

The House Rules Committee is expected to take up the bill this evening. If the ultra-conservative faction of the Rules Committee prevents passage, Speaker Johnson will be forced to bring the bill to the floor under suspension. Either way, he will need to depend on Democratic votes to pass the measure. The Senate will take up the bill as soon as it passes the House, and barring any procedural protests, will pass the CR by the end of the week allowing both chambers to recess until after the November elections.

The House is also scheduled to take up a number of bills under suspension this week including:

- [H.R. 6829](#) – HEARTS Act of 2024, to support the creation and dissemination of cardiomyopathy education, awareness, and risk assessment materials and resources to identify more at-risk families, to authorize research and surveillance activities relating to cardiomyopathy.
- [H.R. 3884](#) – Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act of 2023 to reauthorize the program providing for sickle cell disease and other heritable blood disorders research, surveillance, prevention, and treatment.
- [H.R. 2706](#) – Charlotte Woodward Organ Transplant Discrimination Prevention Act, to prohibit discrimination on the basis of mental or physical disability in cases of organ transplants.
- [S. 133](#) – NAPA Reauthorization Act to extend the National Alzheimer's Project.
- [S. 134](#) – Alzheimer's Accountability and Investment Act to require an annual budget estimate for the initiatives of the National Institutes of Health pursuant to reports and recommendations made under the National Alzheimer's Project Act.
- [H.R. 7189](#) – Congenital Heart Futures Reauthorization Act of 2024, to reauthorize a national congenital heart disease research, surveillance, and awareness program.

- **H.R. 5526** – Seniors’ Access to Critical Medications Act of 2024, to clarify the application of the in-office ancillary services exception to the physician self-referral prohibition for drugs furnished under the Medicare program.
- **H.R. 3433** – Give Kids a Chance Act of 2023, authorizes certain targeted clinical trials involving combinations of drugs to treat pediatric cancer.

Hearings and Markups: There are several hearings and markups scheduled for this week, including:

Senate Finance Committee: On Tuesday, the Senate Finance Committee will **hold** a hearing to examine women’s health care, featuring testimony from obstetricians and gynecologists.

Senate HELP Committee:

- On Tuesday the Senate Committee on Health, Education, Labor, and Pensions will **hold** a hearing to examine Novo Nordisk's high prices for Ozempic and Wegovy for patients with diabetes and obesity.
- On Thursday the Senate Committee on Health, Education, Labor, and Pensions will hold a **markup** to consider bills that would require the Department of Health and Human Services (HHS) to submit a strategic plan for the Human Foods Program of the Food and Drug Administration (FDA), reauthorize the FDA Rare Pediatric Disease Priority Review Voucher Program, eliminate red tape for biosimilars, require reporting on infant formula contamination, and authorize a grant program at HHS to award grants to accredited schools of medicine or osteopathic medicine for the purpose of increasing enrollment of medical students at eligible institutions.

House Oversight Committee: On Thursday the House Oversight and Accountability Subcommittee on Health Care and Financial Services will hold a **hearing** titled “Meddling with Medicare: The Biden-Harris Cover-Up.”

Regulatory Update

The Office of Management and Budget (OMB) completed review the following rule:

- **Fraud** – The **final rule** would modify the Medicare Shared Savings Program (Shared Savings Program) regulations to address the impact of significant anomalous billing patterns on performance year (PY) 2023 Accountable Care Organization (ACO) financial reconciliation (no date).

OMB is also reviewing the following rules:

Medicare

- **Hospital Payment** – The **interim final rule** would make changes to the Medicare hospital inpatient and long-term care hospital prospective payment system for fiscal year (FY) 2025.

- **Medicare Advantage** – The [proposed rule](#) would make policy and technical changes to the Medicare Advantage, Medicare Prescription Drug Benefit, and Medicare Cost Plan Programs, and PACE for contract year 2026 (September 2024).

Private Insurance

- **ACA Marketplace** – The [proposed rule](#) would set payment parameters and provisions related to the risk adjustment programs; cost-sharing parameters; and user fees for issuers offering plans on Federally-facilitated Exchanges and State-based Exchanges using the Federal platform. It would also provide additional standards for several other ACA programs (September 2024).
- **Preventive Services** – The [proposed rule](#) is titled, “Enhancing Coverage of Preventive Services under the Affordable Care Act.” It was not included in the latest Unified Agenda.

Other Topics

- **Healthcare System Resiliency and Modernization** – The [proposed rule](#) would revise and update national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers (was set for December 2023).
- **Retail Pharmacy Standards** – The [final rule](#) would require pharmacies and vendors to modify the currently adopted National Council for Prescription Drug Programs (NCPDP) standards to the Telecommunications Standard Implementation Guide Version F6 (F6); Batch Standard Implementation Guide version 15; and Batch Standard Subrogation Implementation Guide version 10 (was set for February 2024).
- **Organ Transplants** – The [final rule](#) would establish a new mandatory Medicare payment model, the Increasing Organ Transplant Access Model (IOTA Model), that would test whether performance-based incentive payments paid to or owed by participating kidney transplant hospitals increase access to kidney transplants for patients with end-stage renal disease (ESRD) while preserving or enhancing the quality of care and reducing Medicare expenditures.

This Week in Health Policy

Mon. (9/23)

- **9:00am – NIH Meeting: Health Outcomes for Autistic Individuals** – The National Institutes of Health (NIH) holds a meeting of the Office of the Secretary to discuss the 2024 Interagency Autism Coordinating Committee strategic plan update, which is focused on co-occurring conditions and the impacts on health outcomes for autistic individuals. [Details.](#)
- **9:00am – HHS Meeting: Asian Americans/Native Hawaiians/Pacific Islanders Updates** – The Department of Health and Human Services (HHS) holds a meeting of the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders (AA and NHPI) to discuss recommendations by the commission's subcommittees on ways to advance equity, justice, and opportunity for Asian American, Native Hawaiian, and Pacific Islander communities. [Details.](#)

- **11:00am – HITAC Meeting: Annual Report Workgroup** – The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Annual Report Workgroup to discuss program updates. [Details](#).

Tue. (9/24)

- **10:00am – Hearing: Criminalization of Women’s Health Care** – The Senate Finance Committee holds a hearing to examine women’s health care, featuring testimony from obstetricians and gynecologists. [Details](#).
- **10:00am – Hearing: Novo Nordisk’s Prescription Drug Prices** – The Senate Committee on Health, Education, Labor, and Pensions holds a hearing to examine Novo Nordisk’s high prices for Ozempic and Wegovy for patients with diabetes and obesity. [Details](#).
- **10:00am – Hearing: Supreme Court Trump Immunity Ruling** – The Senate Judiciary Committee holds a hearing to examine the Supreme Court’s immunity decision on former President Trump. [Details](#).
- **10:15am – Hearing: TANF Reform** – The House Ways and Means Committee holds a hearing to examine the need to reform the Temporary Assistance for Needy Families (TANF) to target families in need, connect people to work, and improve accountability. [Details](#).
- **12:00pm – Congressional Briefing: Eating Disorders/Mental Health Parity** – REDC holds a congressional briefing on the new mental health parity final rule, including how changes in the rule will improve access to comprehensive, insurance-covered care for mental health and substance use disorders, especially those with eating disorders. [Details](#).

Wed. (9/25)

- **9:30am – Markup: High-Risk Life Sciences Research/FEMA** – The Senate Homeland Security and Governmental Affairs holds a markup to consider S.4667, to establish the Life Sciences Research Security Board, and S.5067, to improve individual assistance provided by the Federal Emergency Management Agency (FEMA), among other bills. [Details](#).
- **10:00am – Hearing: Housing Unaffordability** – The Senate Budget Committee holds a hearing to examine economic risks from housing unaffordability, focusing on the costs of inaction. [Details](#).
- **10:00am – Hearing: Biden-Harris Administration Economic Policy Oversight** – The House Oversight and Accountability Subcommittee on Economic Growth, Energy Policy, and Regulatory Affairs holds a hearing to examine the Biden-Harris Administration economic policies and their impact on consumers. [Details](#).
- **12:00pm – CAP Discussion: Lowering Costs Through Competition** – The Center for American Progress holds a discussion with the Federal Trade Commission (FTC) Chair Linda Khan and Sen. Ray Lujan (D-NM) to discuss the FTC’s efforts to increase competition by improving price transparency and targeting anticompetitive practices. [Details](#).
- **2:00pm – Hearing: Workforce and AI** – The Senate Committee on Health, Education, Labor, and Pensions holds a hearing to examine preparing workers for artificial intelligence (AI). [Details](#).
- **2:00pm – Hearing: Border Crisis Costs** – The House Oversight and Accountability Subcommittee on National Security, the Border, and Foreign Affairs holds a hearing to examine the cost of the border crisis. [Details](#).

Thurs. (9/26)

- **8:00am – CMS Meeting: Oncologic Drugs** – The FDA holds a meeting of the Oncologic Drugs Advisory Committee to discuss the use of immune checkpoint inhibitors in patients with unresectable or metastatic gastric and gastroesophageal junction adenocarcinoma. [Details.](#)
- **9:00am – Consumer Technology Association Discussion: Digital Health Innovations** – The Congressional Digital Health Caucus, co-chaired by Reps. Troy Balderson (R-OH) and Robin Kelly (D-IL), and the Consumer Technology Association for the 2024 host the Digital Health Startup Day on Capitol Hill. The Health Innovation Showcase will highlight cutting-edge innovations in the health sector. Attendees can interact directly with digital health startup companies and participate in product demonstrations. [Details.](#)
- **9:30am – BPC Discussion: Opioid Crisis** – The Bipartisan Policy Center holds a discussion on the opioid epidemic ahead of the election. [Details.](#)
- **9:30am – HHS Meeting: Initiative on AA and NHPIs** – HHS holds a meeting of the President's Advisory Commission on AA and NHPIs to discuss the Biden-Harris Administration's leadership, accomplishments, and continued commitment to advancing equity, justice, and opportunity for AA and NHPI communities. [Details.](#)
- **10:00am – Markup: GME/Biosimilars/Rare Pediatric Diseases/Infant Formula** – The Senate Committee on Health, Education, Labor, and Pensions holds a markup to consider bills that would require the Department of Health and Human Services (HHS) to submit a strategic plan for the Human Foods Program of the Food and Drug Administration (FDA), reauthorize the FDA Rare Pediatric Disease Priority Review Voucher Program, eliminate red tape for biosimilars, require reporting on infant formula contamination, and authorize a grant program at HHS to award grants to accredited schools of medicine or osteopathic medicine for the purpose of increasing enrollment of medical students at eligible institutions. [Details.](#)
- **12:00pm – Axios Discussion: People's View on AI** – AXIOS holds a discussion with Sen. John Hickenlooper (D-CO) and Asad Ramzanali, Deputy Director for Strategy at the White House Office of Science and Technology Policy on the current state of public opinion around AI and what's next for collective oversight over the technology. [Details.](#)
- **2:00pm – Hearing: Biden-Harris Administration Medicare Policy Oversight** – The House Oversight and Accountability Subcommittee on Health Care and Financial Services holds a hearing titled "Meddling with Medicare: The Biden-Harris Cover-Up." [Details.](#)

Additional Multi-Day Events

- **Sep 23-Sep 24 – CAP Discussion: Gun Violence Prevention** – The Center for American Progress (CAP) holds its 10th National Gun Violence Prevention. Includes a presentation on implementing public health approaches to violence prevention. Rep. Robin Kelly (D-IL) will be participating. [Details.](#)
- **Sep 24-Sep 25 – NIST Meeting: Biden EO on AI** – The National Institute of Standards and Technology (NIST) holds a workshop to discuss its implementation of President Biden's 2023 artificial intelligence (AI) executive order (EO), including standards development and uses of the agency's risk management. [Details.](#)
- **Sep 25-Sep 26 – HHS Meeting: Dietary Guidelines** – HHS holds a meeting of the 2025 Dietary Guidelines Advisory Committee to provide subcommittee updates and deliberation by the full committee regarding progress made since the fifth public meeting. [Details.](#)

- **Sep 26-Sep 27 – ACL Meeting: People with Intellectual Disabilities** – The Administration for Community Living (ACL) holds a meeting of the President's Committee for People with Intellectual Disabilities (PCPID) to discuss the 2024 PCPID Report focused on home and community-based services and discuss emerging issues facing people with intellectual disabilities. [Details.](#)

Featured Analysis

- **Impact Preview of Lame Duck Health Package** – In the Policy Hub Insight Bank [here.](#)
- **Impact Chart of PBM Legislation** – In the Policy Hub Insight Bank [here.](#)
- **Impact Regulatory Outlook: Spring 2024 Unified Agenda** – In the Policy Hub Insight Bank [here.](#)
- **Making Sense of the New Landscape for Health Policy After Recent Supreme Court Decisions** – In the Policy Hub Insight Bank [here.](#)
- **Impact Mental Health Legislative Update** – In the Policy Hub Insight Bank [here.](#)

Congressional Lookback

Fri. (9/20)

- **MACPAC** convened virtually for day two of its [September 2024 public meeting](#) and held sessions on residential behavioral health services, managed care external quality review, justice-involved youth, and hospital payment index. All Impact session summaries are available on Policy Hub [here.](#)

Thurs. (9/19)

- **MACPAC** convened virtually for day one of its [September 2024 public meeting](#) and held sessions on timely access to care, HCBS, and PACE. All Impact session summaries are available on Policy Hub [here.](#)

Weds. (9/18)

- **The House E&C Committee** convened a [full committee markup](#) of 16 bills to address a wide range of issues related to health and beyond. [Details.](#)
- **The House W&M Health Subcommittee** convened a [hearing](#) to discuss chronic disease prevention and treatment. [Details.](#)
- **The Senate Agriculture, Nutrition, and Forestry Committee** held a [hearing](#) to discuss the National School Lunch Program (NSLP) and School Breakfast Program (SBP). [Details.](#)

Tues. (9/17)

- **The Senate Finance Committee** convened a [hearing](#) entitled “Lower Health Care Costs for Americans: Understanding the Benefits of the Inflation Reduction Act.” [Details.](#)

Regulatory Lookback

Fri. (9/20)

- **CMS** issued a [final rule](#) to implement new policies in the MDRP to address instances of drug misclassification and increase program integrity. [Details.](#)
- **The ACL** released a [progress report](#) detailing the implementation of the 2022 National Strategy to Support Family Caregivers. [Details.](#)

Thurs. (9/19)

- **CMS and SAMHSA** released several behavioral health comment opportunities. [Details.](#)

Comment & Application Deadlines

- **September 25:** AHRQ issued a [Notice of Funding Opportunity \(NOFO\)](#) aimed at exploring the impact of artificial intelligence (AI) technologies on patient safety. The first application due date is September 25, 2024. The current closing date for applications is May 25, 2027. [Details.](#)
- **September 25:** CMS is [seeking nominations](#) for a Technical Expert Panel (TEP) to refine the Quality Measure Index. [Details.](#)
- **September 26:** The FDA issued [draft guidance](#) entitled “Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies.” [Details.](#)
- **September 30:** The CDC is [seeking nominations](#) for membership on the Healthcare Infection Control Practices Advisory Committee (HICPAC). [Details.](#)
- **October 7:** CMS issued an [RFI](#) seeking information on AI technologies that can improve health care outcomes and service delivery. [Details.](#)
- **February 25:** CMMI released an [RFA](#) for the Cell and Gene Therapy Access Model. [Details.](#)
- **February 25:** CMMI released a [NOFO](#) to apply for Cooperative Agreement funding to support states’ participation in the Cell and Gene Therapy (CGT) Access Model. [Details.](#)